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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE LIDODERM ANTITRUST LITIGATION	MDL DOCKET NO. 2521 Case No. 14-md-2521-WHO
RITE AID CORPORATION and RITE AID HDQTRS. CORP., Plaintiffs, v. ENDO PHARMACEUTICALS INC., TEIKOKU PHARMA USA, TEIKOKU SEIYAKU CO., WATSON PHARMACEUTICALS, INC., ACTAVIS, PLC, and WATSON LABORATORIES, INC. Defendants.	Case No. COMPLAINT JURY TRIAL DEMANDED

Plaintiffs Rite Aid Corporation and Rite Aid Hdqtrs. Corp. (collectively "Plaintiffs") file this Complaint under the antitrust laws of the United States against Defendants Endo Pharmaceuticals Inc. ("Endo"), Teikoku Pharma USA ("Teikoku Pharma"), Teikoku Seiyaku Co. ("Teikoku Seiyaku") (collectively "Teikoku"), and Watson Pharmaceuticals, Inc., Actavis, plc, formerly known as Watson Pharmaceuticals, Inc., and Watson Laboratories, Inc. (collectively "Watson"). For their Complaint, Plaintiffs allege as follows:

I. NATURE OF THE ACTION

1. This is a civil antitrust action brought by purchasers of a lidocaine patch 5% sold by Endo under the brand name Lidoderm. Lidoderm is indicated for the treatment of pain associated

with post-herpetic neuralgia. Plaintiffs seek overcharge damages and other relief arising out of Defendants' unlawful foreclosure of generic competition in the market for lidocaine patch 5%.

2. On May 28, 2012, Endo and Teikoku entered into an unlawful agreement in which they paid Watson to settle a patent infringement case and delay the introduction of generic Lidoderm. Under the agreement (the "Reverse Payment Agreement" or "Agreement"), Watson agreed to delay marketing its less-expensive generic version of Lidoderm for almost 13 months, until September 15, 2013. In exchange, Endo and Teikoku agreed to pay Watson and did, in fact, pay Watson (a) at least $96 million in the form of branded Lidoderm provided at no cost to Watson, which Watson could then resell (and did, in fact, resell) at Endo's prices; and (b) by forbearing from launching an authorized generic to compete with Watson's generic Lidoderm until 7½ months after Watson's generic belatedly entered the market, effectively transferring hundreds of millions of dollars from Endo and Teikoku to Watson. Even though Watson was granted final FDA approval to launch its less-expensive generic Lidoderm patch on August 23, 2012, in compliance with the Agreement, Watson did not come to market until September 15, 2013, thirteen (13) months later.

3. But for Defendants' unlawful Reverse Payment Agreement, one or more generic versions of Lidoderm would have entered the market as early as August 23, 2012. Thus, absent Defendants' unlawful Reverse Payment Agreement, Plaintiffs and/or their assignors would have been able to purchase their requirements of lidocaine patch 5% at significantly lower prices substantially earlier than they did, rather than being forced to pay higher prices for brand and generic Lidoderm because of the unlawful agreement. Endo stated in its annual reports that sales of Lidoderm were $825 million in 2011 and $947 million in 2012.

4. Defendants' unlawful Reverse Payment Agreement was designed to and did in fact: (i) delay and/or preclude the entry of less-expensive generic lidocaine patch 5%; (ii) delay the introduction of an authorized generic lidocaine patch 5%, which otherwise would have appeared on the market at a significantly earlier time and lowered prices further; (iii) fix, raise, maintain or stabilize the prices of lidocaine patch 5%; (iv) permit Endo to maintain a monopoly for lidocaine patch 5%; (v) allocate 100% of the lidocaine patch 5% market in the United States to Endo for up

to 13 months; and (vi) allocate 100% of generic lidocaine patch 5% sales in the United States to Watson for 7½ months.

5. Defendants violated §§ 1 and 2 of the Sherman Act through their anticompetitive Reverse Payment Agreement, which unreasonably restrained competition in the market for lidocaine patch 5% and improperly maintained and extended Endo's market and monopoly power by foreclosing or delaying competition from lower-priced generic versions of lidocaine patch 5%.

II. THE PARTIES

6. Plaintiffs Rite Aid Corporation and Rite Aid Hdqtrs. Corp. (collectively "Rite Aid") are corporations organized and existing under the laws of the State of Delaware with a principal place of business at 30 Hunter Lane, Camp Hill, Pennsylvania 17011. Rite Aid purchases substantial quantities of pharmaceutical products and other goods for resale to the public through nearly 4,600 drugstores operated by its affiliates. Rite Aid brings this action on its own behalf and as the assignee of McKesson Corporation, which during the relevant period purchased Lidoderm directly from Endo for resale to Rite Aid and which has assigned its claims arising out of those purchases to Rite Aid.

7. Defendant Endo is a Delaware corporation, with its principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania, 19355. Endo markets and sells Lidoderm throughout the United States.

8. Defendant Teikoku Seiyaku is a company organized and existing under the laws of Japan, with its principal place of business in Higashikagawa, Kagawa, Japan. Teikoku Seiyaku is the owner, assignee, or licensee of U.S. Patent No. 5,827,529 (the "'529 patent") over which Endo and Teikoku sued Watson. Teikoku Seiyaku manufactures Lidoderm in Japan for commercial sale in the United States by Endo under a Manufacturing and Supply Agreement with Endo. Endo pays Teikoku Seiyaku royalties under that agreement.

9. Defendant Teikoku Pharma is a California corporation, with its principal place of business at 1718 Ringwood Avenue, San Jose, California, 95131. Teikoku Pharma is a wholly-owned subsidiary of Teikoku Seiyaku, and is the holder of the New Drug Application for Lidoderm.

10. Defendant Actavis, plc is incorporated under the laws of Ireland, with its principal place of business at 1 Grand Canal Square, Docklands Dublin 2, Ireland. Actavis, plc also has a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054.

11. Defendant Watson Pharmaceuticals, Inc. was a Nevada corporation, with its principal place of business at 311 Bonnie Circle, Corona, California, 92880. As a result of Watson Pharmaceuticals, Inc.'s acquisition of Actavis Group in or around October 2012, effective on or about January 24, 2013, Watson Pharmaceuticals, Inc. changed its name to Actavis, Inc. Actavis, Inc. changed its name to Actavis, plc on or about October 1, 2013.

12. Defendant Watson Laboratories, Inc. is a Nevada corporation, with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Defendant Watson Laboratories, Inc. was a wholly-owned subsidiary of Watson Pharmaceuticals, Inc. and is now a subsidiary of Actavis, plc.

13. Watson was and is engaged in the marketing, production, and distribution of generic pharmaceutical products, including through its wholly-owned wholesaler affiliates Anda, Inc., Anda Pharmaceuticals, Inc., and Valmed Pharmaceuticals, Inc.

14. All of Defendants' actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

15. With respect to all of the conduct complained of below, Endo at all relevant times acted in concert with its supplier Teikoku. Moreover, Endo, Teikoku Pharma, and Teikoku Seiyaku each signed the Reverse Payment Agreement with Watson. Furthermore, Endo, Teikoku Pharma, and Teikoku Seiyaku at all relevant times acted as a single entity with respect to the material provisions and performance of the Reverse Payment Agreement, which refers to Endo, Teikoku Pharma, and Teikoku Seiyaku collectively in provisions relating to the grant of patent

licenses to Watson, the agreement not to launch a competing authorized generic for 7½ months, and the obligation to deliver free Lidoderm product to pay Watson.

16. As the manufacturer and supplier of Lidoderm to Endo, and as Endo's partner in a joint marketing enterprise relating to the distribution and marketing of Lidoderm in the United States, Teikoku had a financial interest in assisting Endo to maintain its monopoly power by foreclosing and delaying competition from lower-priced generic versions of lidocaine patch 5%.

III. JURISDICTION AND VENUE

17. This action arises under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, and seeks to recover threefold damages and other relief for the injuries sustained by Plaintiffs and/or their assignors resulting from Defendants' unlawful restraint of trade and maintenance of monopoly power in the market for lidocaine patch 5% in the United States. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a).

18. Defendants transact business within this district and carry out interstate trade and commerce in substantial part in this district, and/or have an agent, and/or can be found in this district. Defendant Teikoku has a principal place of business in this district. Venue is therefore appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22, 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1407.

IV. REGULATORY BACKGROUND

A. Characteristics of the Prescription Pharmaceutical Marketplace

19. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit in order to obtain or maintain market power in the sale of particular pharmaceutical compositions. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person both pays for and chooses the products, the price of the product plays an appropriate role in the person's choice of products and, consequently, the manufacturers have an appropriate incentive to compete by lowering product prices.

20. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing certain pharmaceutical products, including Lidoderm, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

21. Endo, Teikoku, and other brand pharmaceutical sellers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

22. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand -- the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is what economists and antitrust courts refer to as market power. The result of the market imperfections and marketing practices described above is to allow brand manufacturers to gain and maintain market power with respect to many branded prescription pharmaceuticals.

B. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs

23. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and

effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

24. When the FDA approves a brand manufacturer's NDA, the drug product is listed in an FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." The manufacturer must list in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. If a brand manufacturer obtains a patent after FDA approval of an NDA, it must subsequently list it in the Orange Book within thirty days of the patent's issuance. 21 U.S.C. §§ 355(b)(1) & (c)(2).

25. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

C. The Hatch-Waxman Amendments

26. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, and must only show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug -- that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to their brand-name counterparts an "AB" rating.

27. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients, having

the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. §355(j)(8)(B).

28. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

29. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historically high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009 total prescription drug revenue had soared to more than $300 billion.

D. Paragraph IV Certifications

30. Under the Hatch-Waxman Act, a manufacturer must make one of four certifications to obtain FDA approval of an ANDA:

i. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand drug has expired (a "Paragraph II certification");

iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

31. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within

forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

32. As an incentive to spur manufacturers to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other generic versions of the drug. For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of market exclusivity (unless some forfeiture event like that discussed below occurs). This means that the first approved generic is the only available generic for at least six months, which effectively creates a duopoly between the brand company and the first-filing generic during this period. This 180-day exclusivity period is extremely valuable to generic companies. When a single generic enters the market, its price, while lower than the branded price, is typically higher than it would be if there were multiple generic competitors on the market. Generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, but this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market. Being able to sell at a higher duopoly price for six months may be worth hundreds of millions of dollars.

33. Brand manufacturers can "game the system" by listing patents in the Orange Book (even if such patents are not eligible for listing) and suing any generic competitor that files an ANDA with a Paragraph IV certification (even if the competitor's product does not actually infringe the listed patents) in order to delay final FDA approval of an ANDA for up to 30 months. That brand manufacturers often sue generics under Hatch-Waxman simply to delay generic competition -- as opposed to enforcing a valid patent that is actually infringed by the generic -- is demonstrated by the fact that generic firms have prevailed in Paragraph IV litigation, by obtaining

a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal, in cases involving 73% of the drug products studied.

34. The first generic applicant can help the brand manufacturer "game the system" because by delaying its own market entry, it can also delay the market entry of all other generic manufacturers. By agreeing not to begin marketing its generic drug, the first generic applicant delays the start of its 180-day period of generic market exclusivity thereby preventing any subsequent generic applicants from coming to market, a tactic called exclusivity "parking." This tactic creates a "bottleneck" because later generic applicants cannot launch until the first generic applicant's 180-day exclusivity expires or is forfeited.

35. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") in order to make it more difficult for brand and generic manufacturers to conspire in order to delay the start of the first-filer's 180-day period of generic market exclusivity. The MMA outlines a number of conditions under which an ANDA applicant forfeits its eligibility for 180-day exclusivity, making way for other ANDA filers to launch their generic products. For example, forfeiture occurs if the first ANDA applicant fails to obtain tentative approval from the FDA within 30 months of filing a substantially complete ANDA, unless the failure is caused by a change in or review of the approval requirements.

36. A first ANDA applicant may also forfeit its 180-day exclusivity if it fails to market its generic drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents that qualified the first applicant for exclusivity (*i.e.*, as to each patent for which the first applicant submitted a Paragraph IV certification), at least one of the following has occurred: (i) a final decision of invalidity or non-infringement is issued; (ii) a settlement order is issued, entering final judgment that includes a finding that the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the Orange Book.

37. Brand manufacturers and first-filing generic manufacturers can structure patent settlements to prevent forfeiture. For example, manufacturers can subvert the failure-to-market provisions and keep the 180-day exclusivity bottleneck in place by, for example, settling their litigation before a final judgment of invalidity or non-infringement with respect to each of the patents for which the first applicant submitted a Paragraph IV certification, or seeking a consent judgment that does not include a finding that all of the patents for which the first applicant submitted a Paragraph IV certification were invalid or not infringed. When that happens, in order to trigger forfeiture and gain access to the market, subsequent ANDA applicants must obtain a judgment that all patents for which the first filing generic company filed Paragraph IV certifications are invalid or not infringed. This may require the subsequent ANDA applicant to initiate a declaratory judgment action concerning patents that the brand manufacturer did not assert against it in a Paragraph IV litigation.

38. In addition, brand and generic manufacturers can structure their settlements in a way that grants 180 days of exclusivity to the generic even where it is likely that the generic has forfeited exclusivity under an MMA forfeiture provision, *e.g.*, if the generic failed to obtain tentative approval within 30 months of submitting a substantially complete ANDA. This results in a windfall to the generic and a subversion of the regulatory scheme. Because the FDA does not typically make a formal 180-day exclusivity determination until another generic applicant has received final approval and is ready to launch, settlements that retain de facto exclusivity -- even where exclusivity should be forfeited de jure under the MMA -- dissuade subsequent generic applicants from trying to obtain a court judgment of invalidity and/or infringement that would trigger the start of the 180-day period. Because the lion's share of generic revenues typically go to the first filer, subsequent filers have less incentive to litigate to judgment.

E. Benefits of Generic Drugs

39. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between generic and brand name drugs is their price: generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic

competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. The launch of a generic drug thus usually results in huge cost savings for all drug purchasers. The Federal Trade Commission ("FTC") estimates that, one year after market entry, the generic version takes over 90% of the brand's unit sales and sells for 15% of the price of the brand name product. As a result, competition from generic drugs is viewed by brand name drug companies such as Endo and Teikoku as a grave threat to their bottom lines.

40. Due to the price differentials between brand and generic drugs, and other institutional features of the pharmaceutical industry, pharmacists presented with a prescription for a brand name prescription drug liberally and substantially substitute a generic version when one is available. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise by writing "dispense as written" or similar language on the prescription).

41. Generic competition enables Plaintiffs and/or their assignors to purchase generic versions of the drug at substantially lower prices.

42. Until a generic version of the brand drug enters the market, however, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices without losing substantial sales. As a result, brand manufacturers, who are well aware of the effect of generics on brand sales, have a strong incentive to delay the introduction of generic competition into the market, including by using tactics such as the Reverse Payment Agreement at issue here.

F. Authorized Generics

43. The 180-day marketing exclusivity to which first-filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during that 180-day period. Such an "authorized generic" is chemically identical to the brand drug, but is sold as a generic product through either the brand manufacturer's subsidiary (if it has one) or through a third-party generic manufacturer. Competition from an authorized generic

during the 180-day exclusivity period substantially reduces the first-filer's revenue, and substantially reduces drug prices for consumers.

44. In its study, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (August 2011) (the "FTC Study"), the FTC found that authorized generics capture a significant portion of sales, reducing the first-filer generic's revenues by approximately 50% on average during the 180-day exclusivity period. The first-filing generic makes significantly less money when faced with competition from an authorized generic because: (1) the authorized generic takes a large share of unit sales away from the first-filer; and (2) the presence of an additional generic in the market causes prices to decrease.

45. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, drug purchasers such as Plaintiffs and their assignors benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

46. As a practical matter, authorized generics are the only means by which brand-name manufacturers engage in price competition with manufacturers of AB-rated generic drugs. Brand-name manufacturers generally do not reduce the price of their branded drug in response to the entry of an AB-rated generic. Instead, they either raise the price to extract higher prices from the small number of "brand-loyal" patients or, more typically, they continue to raise the price of the branded drug at the same intervals and at the same rate at which they raised the price of the drug prior to generic entry.

47. Given the significant negative impact of an authorized generic on the first-filing generic's revenues, a brand manufacturer's agreement not to launch an authorized generic has tremendous value to the generic manufacturer. Brand manufacturers have used such agreements as a way to pay the first-filer to delay its generic product. Such non-competition agreements deprive consumers and other drug purchasers such as Plaintiffs and their assignors of the lower prices resulting from two forms of competition: (1) competition between the branded and generic products; and (2) competition between the generic products.

V. FACTUAL ALLEGATIONS

A. Background

1. Approval of Lidoderm and its Alleged Patent Protection

48. Lidoderm is a prescription lidocaine-containing patch approved to treat pain associated with post-herpetic neuralgia. The active ingredient in Lidoderm is 5% lidocaine. While other drugs are available to treat the same or similar medical conditions, they are not AB-rated to Lidoderm, cannot be automatically substituted for Lidoderm by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to Lidoderm, and are not economic substitutes for, nor reasonably interchangeable with, Lidoderm.

a. Initial Approval of Lidoderm

49. On March 19, 1999, the FDA approved NDA No. 200612, submitted by Hind Health Care, Inc. ("Hind"), which sought to market an adhesive patch containing 5% lidocaine under the brand name Lidoderm. Lidoderm was awarded Orphan Drug Exclusivity by the FDA, meaning that no generic competitor could get FDA approval to market a generic Lidoderm product until March 2006.

50. In 1998, Hind granted Endo the exclusive right to market and distribute Lidoderm in the United States. Hind subsequently transferred full ownership of and responsibility for the Lidoderm NDA to Teikoku, effective June 1, 1999. Teikoku then granted Endo the exclusive right to market and distribute the Lidoderm patch in the United States under Teikoku's NDA, and Endo launched Lidoderm in the United States in 1999.

b. Endo and Teikoku's Acquisition of the Lidoderm Patents

51. Endo and Teikoku owned or obtained assignments of or licenses to a number of patents associated with Lidoderm. Subsequently, Teikoku listed several patents in the Orange Book as covering Lidoderm. As of January 2010 (after Watson had filed ANDA No. 200675, the first ANDA filed as to Lidoderm), Teikoku listed three patents in the Orange Book.

52. The first was U.S. Patent No. 5,411,738 (the "'738 patent"), which is a method of use patent for treating certain types of pain with lidocaine using a topical delivery mechanism and a gel formulation of lidocaine. The second was U.S. Patent No. 5,601,838 (the "'838 patent"),

which is a method of use patent for treating certain types of pain with lidocaine. Both the '738 and '838 patents were assigned to Hind, expired on May 2, 2012, and are referred to collectively as the "Hind patents."

53. The third patent that Teikoku listed in the Orange Book as covering Lidoderm was U.S. Patent No. 5,827,529 (the "'529 patent"), which is a formulation patent for a lidocaine patch. This patent was assigned to Teikoku, and is set to expire on October 17, 2015. Endo is the exclusive licensee of the '529 patent.

54. The '529 patent, titled "External Preparation for Application to the Skin Containing Lidocaine," issued on October 27, 1998 from an application filed on June 10, 1994. That application was a continuation of an application filed on March 30, 1992.

55. The '529 patent claims foreign priority to Japanese Application No. 3-067353, filed March 30, 1991.

56. The '529 patent contains six claims directed generally to a hydrogel transdermal patch containing the active ingredient lidocaine and inactive ingredients or excipients.

57. Claim 1 of the '529 patent claims a patch comprising "a drug-retaining layer placed on a support," in which the drug-retaining layer comprises an "adhesive gel base and 1 to 10% by weight of lidocaine." The claimed "adhesive gel base" consists of three components within specific percentage weight ranges: (i) "0.5 to 50% by weight of a water-soluble high molecular weight substance"; (ii) "30 to 70% by weight of water"; and (iii) "1 to 70% by weight of a water-retaining agent."

c. Endo and Teikoku's Listing of Additional Patents

58. Endo subsequently obtained additional patents from LecTec Corporation ("LecTec") that it and Teikoku claim cover Lidoderm. In July 2008, LecTec had filed patent infringement litigation against Endo and other manufacturers of medicinal patch products in the United States District Court for the Eastern District of Texas (the "LecTec Litigation") over U.S. Patent No. 5,536,263 (the "'263 patent"), and U.S. Patent No. 5,741,510 (the "'510 patent"), both of which are patents for a medicinal adhesive patch. Each of these patents expired on March 30, 2014.

59. Endo settled the litigation with LecTec in November 2009, paying LecTec $23 million in exchange for exclusive licenses to the '263 and the '510 patents for use in the field of prescription pain medications and treatment.

60. Almost a year later, in or about October 2010, Endo granted Teikoku a sublicense under the '510 patent to make and sell prescription pain medications that contain 5% lidocaine in patch dosage form, including Lidoderm.

61. In or about November 2010, Teikoku submitted the '510 patent to the FDA for listing in the Orange Book with respect to Lidoderm.

62. As of January 2011, Endo and Teikoku had four patents listed in the Orange Book related to Lidoderm: the two Hind patents (which expired in May 2012), the '529 patent, and the '510 patent.

63. In or about May 2011, in exchange for $2 million, Endo acquired from LecTec full title to the '263 patent, the '510 patent, and three other patents. The three other patents were (i) U.S. Patent No. 6,096,333 (the "'333 patent"), (ii) U.S. Patent No. 6,096,334 (the "'334 patent"), and (iii) U.S. Patent No. 6,361,790 (the "'790 patent") (collectively with the '263 and the '510 patents, the "Rolf patents," named for one of the inventors). These three patents all cover methods of formulating a medicinal adhesive patch and expired on March 30, 2014. Other than the '510 patent, none of the Rolf patents was listed in the Orange Book with respect to Lidoderm.

2. Watson's ANDA

64. On November 13, 2009, Watson submitted ANDA No. 200675 to the FDA, seeking to market a generic version of Lidoderm. On or about January 14, 2010, Watson notified Teikoku of its November 13, 2009 ANDA filing.

65. Watson's notice letter included a Paragraph IV certification that the commercial manufacture, use, and/or sale of its generic Lidoderm product would not infringe any claim of the '529 patent, and/or that the '529 patent was invalid and/or unenforceable. Watson was the first generic manufacturer to file an ANDA with a Paragraph IV certification with respect to Lidoderm, potentially entitling it to a six-month exclusivity period, free from competition from

any other ANDA-filing generic company. This exclusivity, however, would not have protected Watson from competition from an authorized generic version of Lidoderm.

66. Watson did not submit Paragraph IV certifications as to the Hind patents, which were to expire on May 2, 2012. As a result, the FDA could not approve Watson's ANDA for generic Lidoderm until the Hind patents expired on May 2, 2012.

67. Watson did not make certifications with respect to any of the Rolf patents because they were not listed in the Orange Book until November 2010, a year after Watson filed its ANDA.

68. The FDA granted final approval to Watson's ANDA on August 23, 2012. However, Watson did not launch its approved generic Lidoderm product until September 16, 2013, because of the unlawful Reverse Payment Agreement with Endo and Teikoku (described in more detail below). As suggested by the size of the reverse payments, no patents asserted, or capable of being asserted, by Endo or Teikoku would or could have prevented Watson from launching its approved generic Lidoderm product.

3. Endo and Teikoku's Patent Litigation

69. On February 19, 2010, Endo and Teikoku sued Watson in the United States District Court for the District of Delaware (*Endo Pharm. Inc., et al., v. Watson Labs., Inc.,* Civil Action No. 10-cv-00138-GMS), alleging that Watson's generic Lidoderm infringed the '529 patent (the "'529 Litigation"). As a result of the filing of the '529 Litigation, a 30-month Hatch-Waxman stay of FDA approval applied to Watson's ANDA, which precluded the FDA from approving Watson's ANDA until (i) that stay expired in mid-July of 2012, or (ii) entry of a final judgment that the '529 patent was invalid, unenforceable, and/or not infringed.

70. Watson raised numerous defenses, including that the '529 patent was invalid and/or unenforceable.

71. As the '529 Litigation moved toward trial, Endo filed another suit against Watson. On or about June 29, 2011, Endo filed suit against Watson in the United States District Court for the District of Delaware *(Endo Pharm. Inc. v. Watson Labs., Inc.,* Civil Action No. 11-cv-00575-GMS) (the "Rolf Patent Litigation"), alleging that Watson's generic Lidoderm product would

infringe three of the Rolf patents -- the '333 patent, the '334 patent, and the '510 patent. Only the '510 patent was listed in the Orange Book. Because the Rolf patents were not listed in the Orange Book when Watson filed its ANDA, the Rolf Patent Litigation did not result in a 30-month Hatch-Waxman stay.

a. The '529 Patent Litigation

72. After a June 27, 2011 *Markman* hearing in the '529 Litigation, Judge Sleet rejected Endo's claim construction, thereby strengthening Watson's defense to Endo and Teikoku's infringement claims. The '529 Litigation then proceeded to a bench trial in February 2012, in which Watson presented evidence of the invalidity of the '529 patent, as well as evidence that Watson's generic did not infringe the patent. The evidence at trial was overwhelmingly in favor of Watson, exposing the '529 patent to a determination that it was invalid or unenforceable and that the patent did not cover either the brand product or Watson's generic product.

73. The evidence developed during the '529 Litigation revealed that the same hydrogel transdermal patch technology claimed in the '529 patent had previously been disclosed in multiple pieces of prior art that were not disclosed to the patent examiner, but were well known to Endo and/or Teikoku (the "Teikoku Prior Art"). Each of the pieces of Teikoku Prior Art disclosed a hydrogel transdermal patch formulation substantially similar to that claimed in the '529 patent.

74. Each piece of the Teikoku Prior Art disclosed an "adhesive gel base" consisting of (i) a water-soluble high molecular weight substance; (ii) water; and (iii) a water-retaining agent, all of which fall within the percentage ranges claimed in the '529 patent. Each shared at least one inventor with the '529 patent, and also shared the same applicant, prosecuting attorneys, or assignee with the '529 patent.

75. During prosecution of the '529 patent, the PTO rejected the patent four times, noting that because lidocaine was conventionally used in transdermal patches, it would have been obvious to place lidocaine into available prior art patches. The applicants consistently distinguished other prior art patches cited by the Examiner, arguing that the patch in the '529 patent was "unique." The applicants never disclosed the Teikoku Prior Art to the PTO, or a prior

art patent with the same elements as the '529 patent, which would have showed that the patch technology in the '529 patent was not unique, and in fact had been previously patented. The PTO never cited the Teikoku Prior Art.

76. Each of these prior art references is prior art to the '529 patent because each was publicly available and accessible more than one year before the March 30, 1991 priority date of the '529 patent. Each of the prior art references predated the priority date of the '529 patent by over a year, and thus invalidated the '529 patent. As suggested by the size of the reverse payments, the '529 patent was not capable of preventing Watson from launching its approved generic Lidoderm product.

77. In addition, the '529 patent did not cover Lidoderm and was not infringed by Watson's generic equivalent. The patch formulation disclosed in the '529 patent included a water-soluble high-molecular-weight substance, water, and a water-retaining agent. The water-soluble high-molecular-weight substance and the water-retaining agent were required to be selected from the groups listed in the patent. The groups listed in the '529 patent are known as Markush groups. "A Markush group is a listing of specified alternatives in a patent claim, typically expressed in the form: a member selected from the group consisting of A, B, and C." *Endo Pharm. Inc., et al., v. Watson Labs., Inc.*, slip op. at 1 n.1, No. 10-138 (GMS) (D. Del. June 27, 2011) *(quoting Abbott Labs. v. Baxter Pharm. Prods.*, 334 F.3d 1274, 1280 (Fed. Cir. 2003)).

78. In the '529 patent, the first Markush group related to "a water-soluble high molecular weight substance selected from the group consisting of gelatin, starch, agar, mannan, alginic acid, polyacrylic acid, a salt of polyacrylic acid, dextrin, methylcellulose, methylcellulose sodium, carboxymethylcellulose, carboxymethylcellulose sodium, polyvinyl alcohol, polyvinyl pyrrolidone, copolymer of methyl vinyl ether and maleic anhydride, gum arabic, tragacanth, karaya gum and locust bean gum."

79. The second Markush group related to "a water-retaining agent selected from the group consisting of ethylene glycol, diethylene glycol, polyethylene glycol, glycerin, sorbitol, martitol, propylene glycol and 1,3-butylene glycol."

80. As the District Court held in its *Markman* decision construing those two patent terms, Federal Circuit precedent from 2003 clearly established that both of the relevant Markush groups in the '529 patent were limited to one and only one of the listed alternatives. *Endo Pharm. Inc., et al., v. Watson Lab., Inc.,* slip op. at 1 n.1-2. Under Federal Circuit precedent, the patent could only be interpreted to cover a product that contains only *one* of the substances from each of the two Markush groups.

81. Watson's generic Lidoderm product contained at least *four* water-soluble high-molecular-weight substances, and *three* water-retaining agents. (So does Lidoderm.) Thus, it did not infringe the '529 patent because it contained more than one substance from each Markush group. As a result, Watson's generic Lidoderm did not infringe the '529 patent. As suggested by the size of the reverse payments, the '529 patent was not capable of preventing Watson from launching its approved generic Lidoderm product.

b. The Rolf Patent Litigation

82. The Rolf patents afforded Endo and Teikoku no basis to prevent Watson from launching its approved generic Lidoderm product, either. Endo sued Watson only on some of the Rolf patents (the '510, '333, and '334 patents). Watson raised defenses and counterclaims alleging that those patents were invalid and/or unenforceable and that its product did not infringe them. Endo and Teikoku did not even bother to sue Watson on the '263 patent. The Rolf Patent Litigation barely proceeded past the pleading stage. As suggested by the size of the reverse payments, the Rolf patents posed no reasonable risk to Watson of patent infringement liability.

83. The '510 patent had been asserted by its previous owner, LecTec, against Endo with respect to its Lidoderm product in the LecTec Litigation in 2008. As Endo and Teikoku learned from the LecTec Litigation, the '510 patent was subject to a strong invalidity challenge. The '510 patent was invalid as obvious in view of prior art references that were not submitted to the PTO during the prosecution of the '510 patent. Watson was also aware of the infirmities of the '510 patent from the publicly-filed pleadings in the LecTec Litigation. As suggested by the size of the reverse payments, the '510 patent was incapable of preventing Watson from launching its approved generic Lidoderm product.

84. The '333 and '334 patents also were not infringed by Watson. Indeed, during the LecTec litigation, LecTec did not even sue Endo for infringement of the '333 and '334 patents with respect to Lidoderm. When Endo ultimately settled the LecTec Litigation in November 2009, it only obtained licenses to the '263 and '510 patents, further demonstrating that licenses to the '333 and '334 patents were irrelevant to the use, manufacture, or sale of Lidoderm. Watson's generic patch, a generic equivalent of the Endo patch, similarly would not infringe the '333 and '334 patents.

85. Indeed, Endo did not bother to obtain the rights to the '333 and '334 patents until May 2011, when it bought the rights to all of the Rolf patents from LecTec for just $2 million, further evidence that those patents were incapable of preventing Watson from launching its approved generic Lidoderm product. As suggested by the size of the reverse payments, none of the Rolf patents was capable of preventing Watson from launching its approved generic Lidoderm product.

B. Endo and Teikoku's Reverse Payment Agreement with Watson

86. On or about May 28, 2012 -- after the February 2012 bench trial and as Endo, Teikoku, and Watson were awaiting a decision from Judge Sleet -- Endo and Teikoku entered into an agreement with Watson ending the patent litigation related to Lidoderm. The Reverse Payment Agreement ended the '529 Litigation and the Rolf Patent Litigation, and obviated the need for Judge Sleet to render decisions on the validity, enforceability, and infringement of the patents Endo and Teikoku had asserted against Watson.

87. Under the Agreement, Watson agreed to delay the launch of its generic Lidoderm product until a "Start Date" defined as the earlier of September 15, 2013, the date that another generic product launched (a virtual impossibility), or the day before Watson forfeited its 180-day exclusivity for failing to go to market (also a virtual impossibility):

> Subject to Section 2(d), Watson agrees, on behalf of itself and its Affiliates, that, prior to the Start Date, it and its Affiliates shall not directly or indirectly market, offer to sell, sell, have sold, import, manufacture or have manufactured in the Territory any of Watson's Generic Product. Watson acknowledges and agrees that each of Endo and Teikoku would be irreparably harmed should Watson breach this

> Section 2(e). Nothing in this Agreement shall prohibit or preclude Watson from exercising its rights under 35 U.S.C. § 271(e)(1).[1]
>
> ***
>
> "Start Date" means the earliest of: (i) September 15, 2013; (ii) the date of Launch of any Generic Product other than Watson's Generic Product; or (iii) the last day before Watson would forfeit its 180-day generic drug exclusivity with respect to Watson's Generic Product due to the operation of 21 U.S.C. 355(j)(5)(D)(ii) as a result of a forfeiture event under 21 U.S.C. 355(j)(5)(D)(i)(I).[2]

88. As one *quid pro quo* for Watson's promise to delay entry of its generic Lidoderm product until September 15, 2013, Endo and Teikoku promised to share with Watson the monopoly profits Endo would reap (and share with Teikoku) from Lidoderm's extended market exclusivity by paying Watson at least $96 million (in the form of branded Lidoderm provided by Endo and/or Teikoku at no cost to Watson) at the rate of $12 million per month from January 1, 2013 through August 1, 2013. Watson was free to sell the brand Lidoderm product and retain the full proceeds of those sales. This payment was no different than if Endo had made those sales itself and then Endo and Teikoku turned over the resulting $96 million in cash to Watson. The Agreement specifically provides:

> Endo/Teikoku shall provide, at no cost, to Watson's Wholesaler Affiliate Brand Product of value totaling twelve million dollars ($12,000,000) per month, as measured at the time of each delivery by the then-prevailing Wholesale Acquisition Cost as defined in the Red Book or, if the Red Book is not available, any other comparable U.S. price listing ("WAC"), on the first business day of each month beginning January 1, 2013 and ending August 1, 2013 (for a total of eight (8) months) for Watson's Wholesaler Affiliate's disposal as provided in Section 3(e). Endo shall provide to Watson's Wholesaler Affiliate an invoice with respect to such Brand Product, which invoice shall reflect the transfer of Brand Product to Watson's Wholesaler Affiliate at no cost. Notwithstanding the foregoing, Endo/Teikoku's obligations under this Section 3(b) shall terminate immediately upon the Launch of any Third Party Generic Product in the Territory. The Brand Product provided to Watson's Wholesaler Affiliate by Endo/Teikoku shall have the same NDC number as the Brand Product sold by Endo. In any month in which Endo/Teikoku has provided to Watson's Wholesaler Affiliate any Brand Product under this Section 3(b), and in which a Third Party has Launched a Generic Product in the Territory, Watson shall either (i) return to Endo a pro rata quantity of the Brand Product delivered by Endo/Teikoku during such month, or (ii) reimburse Endo in cash for the value of the Brand Product (based on the WAC measured at the time of delivery by Endo/Teikoku to Watson's Wholesaler Affiliate), in either case for the pro rata portion of the month on and after such Launch…. Such return or reimbursement shall be made by Watson to Endo within

[1] Settlement Agreement at Section 2(e).

[2] *Id.* at Section 1(v).

> five (5) business days of the date of the Launch of a Generic Product in the Territory.[3]
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> * * *
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> The Brand Product supplied by Endo/Teikoku to Watson's Wholesaler Affiliate under Sections 3(b) through (d) may be resold solely by Watson's Wholesaler Affiliate to Third Parties for use solely in the Territory on pricing and other terms determined by Watson's Wholesaler Affiliate in its sole discretion, provided that neither Watson nor any of its Affiliates (including its Wholesaler Affiliate) shall sell, distribute or dispose of Branded Product in any manner that would constitute a Bundled Sale. Watson agrees that its Wholesaler Affiliate will honor all Endo price-related contracts as communicated to all Endo wholesalers from time to time in the ordinary course of business, provided that the price related contracts do not impose any requirements on Watson's Wholesaler Affiliate that would be inconsistent with requirements imposed upon other Lidoderm® wholesalers, and further provided that such price-related contracts shall not conflict with the terms of this Agreement. Watson shall comply with all Applicable Laws in connection with its resale of the Brand Product.[4]

89. Endo and Teikoku also agreed to make additional payments to Watson if Watson did not receive FDA approval for its generic Lidoderm product by January 1, 2014, as well as additional payments if Watson did not receive approval by January 1, 2015. Neither situation came to pass or was expected to come to pass: Watson received final FDA approval on August 23, 2012, within three (3) months of Defendants' execution of the Reverse Payment Agreement

90. As the Agreement expressly provided, this $96 million payment from Endo and/or Teikoku to Watson was expressly to induce Watson to quit its challenge to Endo and Teikoku's patents:

> Endo/Teikoku and Watson agree that the Brand Product provided by Endo/Teikoku to Watson's Wholesaler Affiliate hereunder is a good-faith, bargained-for resolution of the claims at issue in the Litigation. The Brand Product provided hereunder is not contingent on any past or future purchase of any product from Endo or Teikoku by Watson or any of its Affiliates.[5]

91. Through the Agreement, Defendants ensured that Watson's sales of Lidoderm would not result in price competition, but rather that Watson would sell branded Lidoderm at the same supracompetitive prices at which Endo had been selling it. The Agreement provided that Watson would honor all of Endo's price-related contracts with Endo's wholesalers. In fact, Watson

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[3] *Id.* at Section 3(b) (emphasis added).
[4] *Id.* at Section 3(e).
[5] *Id.* at Section 3(i).

maintained the supracompetitive prices for brand Lidoderm throughout the term of the Agreement, generating revenues and profits of close to $96 million from those sales. Watson's sales of branded Lidoderm did not increase output, reduce price, or increase consumer choice; it merely substituted Watson for Endo as the seller of $96 million worth of branded Lidoderm, solely to pay Watson for delaying market entry of its less-expensive generic Lidoderm.

92. As a second payment in exchange for Watson's promise to delay generic Lidoderm until September 15, 2013, Endo promised to delay its launch of an authorized generic version of Lidoderm for 7½ months after Watson's belated launch of generic Lidoderm, unless another ANDA filer entered the market during that time (a virtual impossibility that, in fact, did not occur).

93. Endo was otherwise ready, willing, and able to launch authorized generic Lidoderm simultaneously with Watson's launch. As early as April 2007, Endo and Teikoku specifically agreed that Endo would be the exclusive licensee for authorized generic Lidoderm. As shown below, this no-authorized-generic promise was effectively a payment from Endo and Teikoku to Watson of $170 million or more.

94. Endo's agreement not to launch an authorized generic meant that Endo ceded those sales to Watson (and Teikoku would forego any proceeds from those sales). As a result, Watson would be the sole generic on the market for 7½ months. This period of contractual exclusivity would allow Watson to obtain 100% of generic Lidoderm sales for 7½ months (instead of roughly 50% if Endo had launched an authorized generic). It also permitted Watson to avoid the inter-generic price competition that an authorized generic necessarily creates and thereby maintain an artificially-inflated, supracompetitive generic price on the roughly doubled generic sales that it would have expected under the agreement. These doubled revenues and profits were at the expense of Plaintiffs, their assignors, consumers, and competition. The Agreement (which refers to an authorized generic by the acronym "AG") provided:

> License. Subject to the terms and conditions of this Agreement, Endo/Teikoku hereby grant to Watson a non-exclusive (other than pursuant to Section 2(b)), royalty-bearing, non-transferable (other than pursuant to Section 21) and non-sublicensable (other than pursuant to Section 2(c)) license to the Licensed Patents

> to make, have made, import, use, sell, and offer for sale Watson's Generic product in the Territory solely during the License Term.[6]
>
> AG Product. The license granted pursuant to Section 2(a) shall be partially exclusive for a period of time in that Endo/Teikoku and their respective Affiliates shall not market or sell a Generic Product, or authorize or license a Third Party to market or sell an AG Product at any time before the earlier of (i) seven and a half (7.5) months from the Start Date, and (ii) the Launch of any Third Party Generic Product in the Territory.[7]

95. Endo's agreement not to launch an authorized generic for 7½ months allowed Watson to double its unit sales *and* charge higher prices for its generic during that time (because it faced no competition from an authorized generic), and had a cash value to Watson of $170 million or more.

96. Absent the Reverse Payment Agreement and Endo's promise not to launch an authorized generic, Endo would have launched an authorized generic simultaneously with Watson's entry, which would have resulted in lower prices to Plaintiffs and their assignors and cut Watson's revenues and profits from selling generic Lidoderm by at least half.

97. In fact, immediately following the expiration of its no-authorized-generic promise, Endo launched an authorized generic.

98. The Reverse Payment Agreement contained a term whereby Watson agreed to pay back to Endo a small (25%) portion of Watson's increased profits resulting from Endo's agreement not to launch an authorized generic for 7½ months. That term provided: "Beginning with the First Commercial Sale of Watson's Generic Product and until the date of the occurrence of the First Commercial Sale by a Third Party or Endo/Teikoku or their Affiliates of a Generic Product or AG Product in the Territory, Watson shall pay to Endo royalty payments equal to twenty-five percent (25%) of all Gross Profit of Watson's Generic Product."[8]

99. This 25% royalty to Endo during the 7½ month period was window dressing for the parties' naked agreement not to compete during Watson's anticipated 180-day Hatch-Waxman exclusivity period. The royalty was designed to create the appearance of a legitimate, non-

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[6] Settlement Agreement at Section 2(a).
[7] *Id.* at Section 2(b) (emphasis added).
[8] *Id.* at Section 3(a).

collusive transaction. In reality, Defendants simply agreed to lengthen the no-authorized-generic promise's duration by 1½ months (from 6 months to 7½ months) in order to mitigate the royalty Watson agreed to pay to Endo.

100. As alleged below, Plaintiffs accounted for the 25% royalty paid by Watson back to Endo in estimating that the value of the payment that Endo and Teikoku made to Watson in the form of the no authorized generic agreement was $170 million or more.

101. Endo and Teikoku sacrificed substantial revenues and profits by their agreement not to launch an authorized generic for 7½ months. Absent the Reverse Payment Agreement and the delay in generic Lidoderm competition it effectuated, it would have made economic sense for Endo to launch an authorized generic simultaneously with Watson's launch so that Endo could retain sales that Watson's less expensive generic otherwise would capture. As alleged above, an authorized generic product typically captures approximately 50% of the generic sales during first 180 days of generic marketing.

102. The no-authorized-generic promise was a very large payment to Watson. A conservative estimate relying on the revenues that Endo reported in its filings with the Securities and Exchange Commission values the no-authorized-generic promise by Endo and Teikoku to Watson at $170 million or more. This estimated value is based on the difference between Watson's revenues during its first 7½ months on the market without any competition from Endo's authorized generic and what Watson's revenues would have been during those 7½ months had Watson faced competition from Endo's authorized generic. Both of these amounts can in turn be estimated using the known dynamics of the pharmaceutical industry and publicly-available information.

103. The revenue that Watson would expect to earn from sales of generic Lidoderm during its first 7½ months on the market without competition from Endo's authorized generic can be estimated as follows:

a. In 2011, the year before Defendants entered the Agreement, Endo reported that its annual revenue from sales of Lidoderm was $825 million. Thus, at the

time of the Agreement, 7½ months of branded Lidoderm sales would generate revenue to Endo of at least $515,625,000 (7.5/12 * 825,000,000).[9]

b. The first generic is typically expected to take 80% (or more) of the brand's unit sales within six months. Thus, approximately $412,500,000 worth of brand unit sales would be converted to Watson's generic during the first 7½ months that Watson's generic Lidoderm was on the market (515,625,000 * .8).

c. With only one generic on the market, the generic is typically priced at 90% of the brand's pre-generic price, which would result in generic sales revenues during the first 7½ months that Watson was on the market of approximately $371,250,000 (412,500,000 * .9). Thus, Watson would expect revenues of approximately $371,250,000 from generic Lidoderm during the 7½ months that the no-authorized-generic promise was in effect.

d. Under the Agreement, Watson agreed to pay Endo a royalty of 25% on Watson's gross profits on sales of generic versions of Lidoderm during the 7½ month period that the no-authorized-generic promise was in effect. Conservatively applying the royalty on $371,250,000 in sales (as opposed to Watson's gross profits, which would be lower), and further assuming that the royalties were actually paid produces an estimated royalty of approximately $92,812,500 (371,250,000 * .25). As a result, even after deducting the amount of the royalty, Watson's anticipated revenue during its first 7½ months on the market without competition from Endo's authorized generic would conservatively be $278,437,500 (371,250,000 - 92,812,500).

104. Watson's expected revenues if Endo had not promised to refrain from launching an authorized generic for 7½ months following Watson's launch are dramatically lower. They can be estimated as follows:

[9] This estimate is conservative, as it does not account for any increase in sales achieved by Endo in 2012 and 2013, during the period of delayed generic Lidoderm competition purchased by Endo and Teikoku's payments to Watson. In fact, Endo's Lidoderm revenue rose from $825 million in 2011 to $947 million in 2012.

a. According to an FDA study of generic competition, the addition of a second generic (such as Endo's authorized generic) drives the average generic price down to 52% of the brand price.[10] Thus, while the generics would still take 80% of brand sales during the first 7½ months, or $412,500,000 at the branded Lidoderm price, the estimated dollar value of the generic sales with an authorized generic on the market would drop to $214,500,000 (412,500,000 * .52).

b. With an authorized generic on the market, Watson would not expect to earn 100% of the generic revenues. Unit sales of the generic during the first 7½ months would be split roughly in half between Watson's generic Lidoderm and Endo's authorized generic Lidoderm.[11] (This is conservative because there is reason to expect that Endo may have enjoyed a marketing advantage as the incumbent and could have garnered more than 50% of unit sales.)

c. Thus, if Watson faced competition from an authorized generic during its first 7 ½ months on the market, an estimate of its revenues during that period would be $107,250,000 (214,500,000 * .5).

105. Accordingly, a reasonable estimate of the incremental revenue that Endo and Teikoku paid Watson through the no-authorized-generic promise is $171,187,500 (278,437,500 - 107,250,000). This estimate assumes that the 25% royalty that Watson agreed to pay during the first 7 ½ months that its generic Lidoderm was on the market should be considered as an offset of the revenues that it expected under the no-authorized generic agreement but not of its expected revenues without the no-authorized generic agreement. This assumption would be appropriate if, for example, Watson was competing with an authorized generic as a result of entering the market:

[10] Generic Competition and Drug Prices, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm (last accessed April 14, 2015).

[11] FTC Study at vi (The FTC has concluded that, when free from competition from an authorized generic, "the first-filer's revenue will approximately double" during the first six months of generic competition, compared to what the first filer would make if it faced authorized generic competition.). The Supreme Court has recognized this as well. *See Federal Trade Comm'n v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013) (the "vast majority of potential profits for a generic drug manufacturer materialize during" the first six months of marketing).

(1) "at risk" before resolution of the patent litigation; (2) after winning the patent litigation; or (3) through an alternate settlement without reverse payments in which Watson did not pay the royalty to extend the period of exclusivity from 6 months to 7 ½ months.

106. An alternate estimate of the value of the no-authorized generic agreement might be appropriate if it were demonstrated that the 25% royalty was not paid as part of the no authorized generic agreement and would have been a term of an alternate settlement without any reverse payments. If in the case of such an alternate settlement, Watson agreed to pay a royalty of 25% during the first 7½ months that Watson's generic was on the market, the royalty on those sales would be approximately $26,812,500 (107,250,000 * .25). Thus, an estimate of the revenue net of royalties in this scenario would be $80,437,500 (107,250,000 - 26,812,500).

107. Under this alternative, the estimate of the value of the no-authorized-generic promise is approximately $198,000,000 (278,437,500 -80,437,500).

108. Thus, the value of the payment that Endo made to Watson by agreeing not to launch an authorized generic Lidoderm for 7½ months was at least $170 million and possibly $198 million or more. And, given that Lidoderm revenues increased significantly to $947 million in 2012, the size of the payment almost certainly increased by the time Watson ultimately received it in September of 2013, when Watson belatedly launched generic Lidoderm without competition from Endo's authorized generic.

109. The total payment flowing from Endo and Teikoku to Watson, including both the $96 million in free goods and Endo's promise to delay the launch of an authorized generic Lidoderm for 7½ months had a cash value in the hundreds of millions of dollars. While it is not Plaintiffs' burden of production or proof to anticipate Defendants' affirmative defenses, Plaintiffs nevertheless allege that Defendants can offer no cognizable, nonpretextual justification or explanation for these reverse payments. The reverse payments are far greater than Endo and Teikoku's avoided litigation costs, and were not for services to be provided by Watson to Endo and/or Teikoku. Rather, the reverse payments were made in order to induce Watson to stay out of the lidocaine patch 5% market until September of 2013 and to allow Defendants to share monopoly profits.

110. These large, unjustified payments have no rational connection to, and far exceed, any approximation of the costs of continuing the patent litigation. Moreover, Defendants cannot possibly establish that either payment was consideration for the fair value of any services provided by Watson to Endo and/or Teikoku. Indeed, Watson was not required to perform any services in exchange for the unlawful payment according to the Reverse Payment Agreement. Watson provided no value to Endo or Teikoku under the Agreement other than its impermissible agreement to delay competition. The Agreement was not a distribution agreement, and Endo had no need for any such services for Lidoderm in any event.

111. Absent Endo and Teikoku's unlawful reverse payments to Watson, any agreement settling the patent litigation would have permitted Watson to enter the market much earlier than the date agreed to as a result of the payments. But for the reverse payments, Watson would have launched much earlier than September 2013, either under an agreement without any reverse payments, or at risk after final approval. And, in either circumstance, Watson's entry would have been immediately met with Endo's authorized generic.

C. Anticompetitive Purpose and Effect of Defendants' Conduct

112. The unlawful Reverse Payment Agreement enabled Defendants to: (a) delay the entry of less expensive generic Lidoderm in the United States for up to 13 months; (b) delay the introduction of an authorized generic lidocaine patch 5% for 7½ months, which otherwise would have appeared on the market coincident with initial generic competition; (c) fix, raise, maintain or stabilize the price of lidocaine patch 5% products; (d) maintain a monopoly in the U.S. market for lidocaine patch 5% products; (e) allocate 100% of the United States market for lidocaine patch 5% to Endo for up to 13 months; and (f) allocate 100% of United States sales of generic lidocaine patch 5% to Watson for 7½ months.

113. But for the unlawful Agreement: (a) Watson would have begun selling its generic version of Lidoderm when it received FDA approval on August 23, 2012 or shortly thereafter, either "at risk" or pursuant to an agreement with Endo and Teikoku that did not include a reverse payment; and (b) Endo would have launched an authorized generic lidocaine patch 5% simultaneously with Watson's earlier entry.

114. Watson would have launched its generic product notwithstanding any patents that Endo and Teikoku may have claimed covered Lidoderm, prior to resolution of the '529 Litigation, and prior to resolution of the Rolf Patent Litigation. None of the patents other than the '529 patent was even listed in the Orange Book when Watson filed its ANDA. Thus, Watson was not required to certify to any other patents under Hatch-Waxman, and any litigation filed over those other patents would not, and could not, result in a 30-month Hatch-Waxman stay of FDA approval of Watson's ANDA. Furthermore, given the obvious defects in the '529 patent and Rolf patents, Watson would have launched upon final FDA approval even in the absence of a court ruling on those patents. Once Watson obtained FDA approval of its ANDA, it was free to launch, and but for the unlawful reverse payments, Watson would have launched its generic Lidoderm immediately, and Endo would have launched an authorized generic simultaneously.

115. Watson told Wall Street analysts in late 2011 and early 2012 that it was pursuing its ANDA, it was closely monitoring the progress of the ANDA and expected approval in 2012, its efforts to increase capacity were well underway, and it expected to be "ready to go at the earliest possible time to launch the product."

116. Alternatively, but for the unlawful reverse payments, Endo, Teikoku, and Watson would have entered into a procompetitive settlement agreement under which Endo and Teikoku would not have paid Watson for delay, Watson would have entered the market much earlier than September of 2013, and Endo would have simultaneously launched an authorized generic lidocaine patch 5%.

117. Defendants' unlawful actions have delayed the sale of generic Lidoderm in the United States, delayed the sale of an authorized generic Lidoderm in the United States, and unlawfully enabled Endo, and then Watson, to sell lidocaine patch 5% at artificially inflated, supracompetitive prices. But for Defendants' illegal conduct, generic competition to Lidoderm would have begun prior to September 15, 2013, and would have included both Watson's generic Lidoderm product as well as Endo's authorized generic Lidoderm.

VI. INTERSTATE COMMERCE

118. The drugs at issue in this case are sold in interstate commerce. Defendants' unlawful activities, as alleged above, have occurred in, and have had a substantial impact on, interstate commerce.

VII. MONOPOLY POWER AND MARKET DEFINITION

119. Endo had market and/or monopoly power over lidocaine patch 5% because it had the power to maintain lidocaine patch 5% prices at supracompetitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Lidoderm until the introduction of AB-rated generic Lidoderm.

120. A small but significant, non-transitory price increase for Lidoderm by Endo would not have caused a significant loss of sales to drug products other than AB-rated generic versions of Lidoderm.

121. Lidoderm does not exhibit significant, positive cross elasticity of demand with respect to price with any product other than AB-rated generic Lidoderm.

122. Because of, among other reasons, its approved indication, Lidoderm is differentiated from all products other than AB-rated generic Lidoderm.

123. Products are considered to be economic substitutes in the same antitrust market if one product constrains the ability of a seller of the other product to profitably raise its price above competitive levels. Only AB-rated generic Lidoderm is sufficiently interchangeable with branded Lidoderm to prevent Endo from raising or maintaining the price of Lidoderm above competitive levels.

124. Endo sold Lidoderm at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

125. Endo had, and exercised, the power to exclude and restrict competition for Lidoderm and its AB-rated generics.

126. Endo and Teikoku's reverse payments of hundreds of millions of dollars to Watson demonstrate that Endo enjoyed market and/or monopoly power with respect to lidocaine patch 5%.

127. Endo, at all relevant times, enjoyed high barriers to entry with respect to the above-defined relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

128. To the extent that Plaintiffs may be legally required to prove market and/or monopoly power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant market is lidocaine patch 5% (*i.e.*, Lidoderm and its AB-rated generic equivalents). During the period relevant to this case, Endo was able to profitably maintain the price of lidocaine patch 5% well above competitive levels.

129. The relevant geographic market is the United States.

130. Prior to September 15, 2013, Endo's market share in the relevant market was 100%, implying a substantial amount of market power.

VIII. EFFECT ON COMPETITION AND DAMAGES

131. Watson's ANDA was approved August 23, 2012. Were it not for the unlawful reverse payments and Reverse Payment Agreement alleged herein, Watson would have entered the market on or shortly after that date. One or more generic Lidoderm products would have entered the market well before September 15, 2013, the date provided in Defendants' unlawful Reverse Payment Agreement.

132. But for the unlawful Reverse Payment Agreement, an authorized generic version of Lidoderm would have been available on the market simultaneously with the launch of Watson's generic.

133. Defendants' unlawful reverse payments and Reverse Payment Agreement delayed generic Lidoderm competition and unlawfully enabled Endo to sell Lidoderm without generic competition. But for Defendants' illegal conduct, one or more generic competitors would have begun marketing AB-rated generic versions of Lidoderm on August 23, 2012 or shortly thereafter, and, in any event, earlier than September 15, 2013.

134. Watson has extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs, marketing generic pharmaceutical products, and manufacturing commercial launch quantities adequate to meet market demand.

135. Defendants' unlawful Reverse Payment Agreement, which delayed introduction of generic versions of Lidoderm in the United States, has caused Plaintiffs and/or their assignors to pay more than they would have paid for lidocaine patch 5%.

136. But for Defendants' unlawful Agreement, Plaintiffs and/or their assignors would have paid less for lidocaine patch 5% by (a) substituting purchases of less-expensive AB-rated generic Lidoderm for their purchases of more-expensive brand Lidoderm, and/or (b) purchasing generic Lidoderm at lower prices sooner.

137. Thus, Defendants' unlawful conduct deprived Plaintiffs and their assignors of the benefits of competition that the antitrust laws were designed to protect.

138. During the relevant period, Plaintiffs and/or their assignors purchased substantial amounts of Lidoderm directly from Endo and purchased substantial amounts of generic Lidoderm directly from Watson. As a result of Defendants' illegal conduct as alleged herein, Plaintiffs and/or their assignors were compelled to pay, and did pay, artificially inflated prices for their lidocaine patch 5% requirements. Plaintiffs and/or their assignors paid prices for lidocaine patch 5% that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Plaintiffs and/or their assignors were deprived of the opportunity to purchase lower-priced generic Lidoderm instead of more expensive brand Lidoderm; and (2) Plaintiffs and/or their assignors paid artificially inflated prices for generic Lidoderm.

139. As a consequence, Plaintiffs and/or their assignors have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial. Plaintiffs' injury is injury of the type the antitrust laws were designed to prevent and flows from that which makes Defendants' acts unlawful.

140. Defendants' conduct threatens continuing loss and damage to Plaintiffs and/or their assignors unless enjoined by this Court.

IX. CLAIMS FOR RELIEF

CLAIM I: VIOLATION OF 15 U.S.C. § 1
(Conspiracy in Restraint of Trade)

141. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 140 above as though fully set forth herein.

142. Defendants have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

143. In or about May 2012 and at times prior to the formal execution thereof, Defendants entered into the Reverse Payment Agreement, an illegal contract, combination, and conspiracy in restraint of trade under which Endo and Teikoku agreed to make large reverse payments to Watson in exchange for Watson's agreement to delay its generic Lidoderm for up to 13 months. The purpose and effect of this illegal Reverse Payment Agreement were to: (a) delay the entry of less expensive generic Lidoderm in the United States for up to 13 months; (b) delay the introduction of an authorized generic lidocaine patch 5% for 7½ months, which otherwise would have appeared on the market coincident with initial generic competition; (c) fix, raise, maintain or stabilize the price of lidocaine patch 5% products; (d) maintain a monopoly in the U.S. market for lidocaine patch 5% products; (e) allocate 100% of the United States market for lidocaine patch 5% to Endo for up to 13 months; and (f) allocate 100% of United States sales of generic lidocaine patch 5% to Watson for 7½ months.

144. The Agreement was likely to have a substantial adverse effect on competition in the relevant market and is unlawful under the rule of reason.

145. In the alternative, the Agreement constitutes a horizontal market allocation agreement that allocated the market temporally rather than geographically and is unlawful *per se*.[12]

[12] This allegation is included to preserve Plaintiffs' appellate rights. Plaintiffs understand that the Court has rejected the contention that Defendants' agreement is unlawful *per se* (Case No. 14-md-2521, ECF Doc. 117, at 26-27) and do not dispute that the Court would reach the same result in this case.

146. There is and was no legitimate, non-pretextual, procompetitive justification for the payments from Endo and Teikoku to Watson that outweighs its harmful effect. Even if there were some conceivable justification, the payment was not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

147. As a direct and proximate result of Defendants' agreement in restraint of trade, as alleged herein, Plaintiffs and/or their assignors were harmed and suffered overcharge damages as set forth above.

CLAIM II: VIOLATION OF 15 U.S.C. § 2
(Conspiracy to Monopolize)

148. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 140 above as though fully set forth herein.

149. At all relevant times, Endo possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Endo possessed the power to control prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

150. Through the Reverse Payment Agreement, Endo, Teikoku, and Watson conspired to maintain Endo's monopoly power in the relevant market in order to block and delay market entry of generic Lidoderm.

151. The Reverse Payment Agreement: (a) delayed the entry of less expensive generic Lidoderm in the United States for up to 13 months; (b) delayed the introduction of an authorized generic lidocaine patch 5% for 7½ months, which otherwise would have appeared on the market coincident with initial generic competition; (c) fixed, raised, maintained or stabilized the price of lidocaine patch 5% products; (d) maintained a monopoly in the U.S. market for lidocaine patch 5% products; (e) allocated 100% of the United States market for lidocaine patch 5% to Endo for up to 13 months; and (f) allocated 100% of United States sales of generic lidocaine patch 5% to Watson for 7½ months.

152. The goal, purpose, and/or effect of the Agreement was to maintain and extend Endo's monopoly power in the United States in the market for lidocaine patch 5%, in violation of Sherman Act Section 2, 15 U.S.C. § 2. The Agreement was intended to and did prevent and/or

delay generic competition to Lidoderm and enabled Endo to continue charging supracompetitive prices for Lidoderm without a substantial loss of sales.

153. Defendants knowingly and intentionally conspired to maintain and enhance Endo's monopoly power in the relevant market.

154. Defendants specifically intended that their Agreement would maintain Endo's monopoly power in the relevant market, and injured Plaintiffs and/or their assignors thereby.

155. As a direct and proximate result of Defendants' concerted monopolistic conduct, as alleged herein, Plaintiffs and/or their assignors were harmed and suffered overcharge damages as set forth above.

CLAIM III: VIOLATION OF 15 U.S.C. § 2
(Monopolization)

156. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 140 above as though fully set forth herein. This claim is asserted against Endo only.

157. At all relevant times, Endo possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Endo possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

158. Through the anticompetitive conduct, as alleged extensively above, Endo willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of a superior product, greater business acumen, or historic accident, and injured Plaintiffs and/or their assignors thereby.

159. Endo's conscious objective was to further its dominance in the relevant market by and through the anticompetitive conduct alleged herein.

160. Endo's anticompetitive conduct harmed competition as alleged herein.

161. As a direct and proximate result of Endo's illegal and monopolistic conduct, as alleged herein, Plaintiffs and/or their assignors were harmed and suffered overcharge damages as set forth above.

CLAIM IV: VIOLATION OF 15 U.S.C. § 2
(Attempt to Monopolize)

162. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 140 above as though fully set forth herein. This claim is asserted against Endo only.

163. Through the Reverse Payment Agreement, Endo specifically intended to maintain monopoly power in the relevant market. Endo's conscious objective was to control prices and/or to exclude competition in the relevant market.

164. The natural and probable consequence of Endo's anticompetitive conduct, which was intended by Endo and plainly foreseeable to Endo, was to control prices and exclude competition in the relevant market.

165. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Endo would succeed in and achieve its goal of maintaining monopoly power in the relevant market.

166. As a direct and proximate result of Endo's illegal and monopolistic conduct, Plaintiffs and/or their assignors were harmed and suffered overcharge damages as set forth above.

X. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment against Defendants and grant the following relief:

A. A declaration that the conduct alleged herein is in violation of Sections 1 and 2 of the Sherman Act;

B. Permanent injunctive relief enjoining Defendants from continuing their illegal conduct and requiring them to take affirmative steps to dissipate the continuing effects of their prior conduct;

C. An award of Plaintiffs' overcharge damages, in an amount to be determined at trial, trebled;

D. An award of Plaintiffs' costs of suit, including reasonable attorneys' fees as provided by law; and

E. Such other and further relief as the Court deems just and proper.

XI. JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable.

Dated: April 21, 2015

Respectfully submitted,

/s/ Anna T. Neill

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